REMARKS/ARGUMENTS

By this Amendment, claims 4, 11-13 are canceled, claims 1 and 5 are amended, and claim 14 is added. Claims 1-3, 5-10, 14 are pending.

Citations to the Specification are directed to U.S. Patent Application Publication No. 2006/0041140.

Support for the amendments to the claims can be found throughout the Specification as filed, and specifically: support for the limitation in claim 1 for hydrogen using platinum oxide, palladium-carbon, raney nickel or ruthenium oxide catalyst in a solvent in the presence of an acid in the quantities ranging from 0.1 to 10 moles of the acid per mole of the compound of formula II can be found in ¶[0018] and ¶[0032]; support for the limitation in claim 1 for "a solvent" can be found in ¶[0032] and ¶[0033]; support for the solvents in claim 14 can be found in ¶[0032] and ¶[0033].

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Rejection under 35 USC 102(b)

Pending claims 1-2, 5-6, 8-10 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Dubroeucq et al. US 4,357,337.

The Examiner cites column 9, example 4, of the '337 patent, pyridylmethyl indanone, acetic acid, platinum oxide and hydrogenation under 1 bar, and argues that this anticipates claims 1, 4-6, and 8-10. The Examiner cites column 13, example 10 of the '337 patent, and argues that this anticipates claim 2.

In Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP 2131), the CAFC set forth that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". In the instant case, not every element of the claims is present in the '337 Dubroeucq patent.

The '337 Dubroeucq patent discloses a process in which 2-[(4-pyridyl)methyl]-2,3-dihydro-1-1H-indenone (0.269 moles) is hydrogenated at the ambient temperature, under a pressure of 1 bar of hydrogen, in the presence of platinum oxide, in acetic acid solvent (37 moles) to give 2[(4-piperidinyl)methyl]-2,3-dihydro-1-1H-indenone (see '337 patent at column 9, example 4). The '337 patent discloses a method utilizing acetic acid as a solvent but not as a catalyst (about 37 moles of acetic acid per mole of the 2-[(4-pyridyl)methyl]-2,3-dihydro-1-1H-indenone is used).

However, in contrast, the instantly claimed method utilizes the acid, in the hydrogenation reaction, as a catalyst (0.1 to 10 moles of the acid per mole of the compound of formula II, for example see page 3, ¶[0018] of US 2006/0041140), in a suitable solvent (see page 4, ¶[0033] of US 2006/0041140) using platinum oxide, palladium-carbon, raney nickel or ruthenium oxide catalyst under a hydrogen pressure of 1 to 10 bars. Therefore, the present invention does not use acetic acid as a solvent in the hydrogenation reaction. Thus, the '337 patent does not disclose all the limitations of the claims.

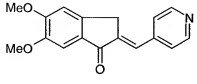
Accordingly, reconsideration and withdrawal of the rejection of pending claims 1-2, 5-6, 8-10 under to 35 USC § 102(b) is respectfully requested.

Rejection under 35 USC 102(e)

Pending claims 1-3, 5-10, 14 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Vidyadhar et al. US 6,649,765.

The Examiner cites column 3, example 1 of the '765 Vidyadhar patent, and argues that this anticipates the instant claims, and notes that 30 psi is 2.068 bar. The Examiner further cites column 4, example 2 of the '765 Vidyadhar patent, and argues that this anticipates the further step of N-alkylation, as set forth in claims 11-12.

The '765 Vidyadhar patent describes a process for preparing donepezil hydrochloride which comprises hydrogenating 5,6-dimethoxy-2-(pyridin-4-yl)-methylene-inda-1-one of formula A:



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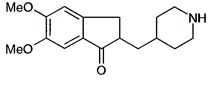
with a noble metal oxide catalyst in an organic solvent. The '765 Vidyadhar patent discloses that the organic solvent can be tetrahydrofuran, methanol, acetic acid, or combination thereof preferably acetic acid-methanol mixture (see the '765 Vidyadhar patent at column 3, lines-26 to 29) to give 4-[(5,6-dimethoxy-1-indanon)-2-yl]methylpiperidone of formula B:



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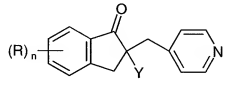
followed by alkylation to give donepezil, which is further converted to donepezil hydrochloride. Hydrogenation of such conjugated systems. Conjugation of alkene double bond with pyridine system is normally easier than the hydrogenation of pyridine system unconjugated with alkene.

However, the instant claims are not drawn to hydrogenation of 5,6-dimethoxy-2-(pyridin-4-yl)-methylene-inda-1-one of formula A, but instead are drawn to hydrogenating the compound of formula II:



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which is clearly a different compound than the formula A compound as set forth in the '765 Vidyadhar patent. As can be seen, the compound of formula II has no double bond in conjugation with a pyridine system, and the claims are not directed to a method for synthesis with hydrogen using platinum oxide, palladium-carbon, raney nickel or ruthenium oxide catalyst in the presence of an acid (0.1 to 10 moles of the acid per mole of the compound of formula II, please see page 3, para-0018 of US 2006/0041140 A1) in a suitable solvent (see page 4, ¶[0033] of US 2006/0041140) under a hydrogen pressure of 1 to 10 bars.

Moreover, in the process exemplified in the '765 Vidyadhar patent (see column 3, example 1), 5,6-dimethoxy-2-(pyridin-4-yl)-methylene-inda-1-one (0.035 moles) is hydrogenated with platinum dioxide under 30 psi gauge hydrogen pressure in a solvent mixture containing acetic acid-methanol (200ml:200ml, i.e., about 94 moles of acetic acid per mole of the

5,6-dimethoxy-2-(pyridin-4-yl)-methylene-inda-1-one is used). In contrast, the instantly claimed method utilizes the acid, in the hydrogenation reaction, as a catalyst in the presence of a suitable solvent (see page 4, ¶[0033] of US 2006/0041140). The instantly claimed method does not use acetic acid as a solvent in the hydrogenation reaction.

Accordingly, reconsideration and withdrawal of the rejection of pending claims 1-3, 5-10, 14 under to 35 USC § 102(e) is respectfully requested.

Rejection under 35 USC 103(a)

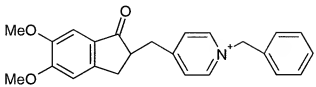
Pending claims 1-3, 5-10, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubroeucq et al. '337 or Vidyadhar et al. '765 in view of Iimura US 6,252,081.

The Examiner alleges that Dubroeucq '337 or '765 Vidyadhar discloses anticipatory processes against the claims when Y is H. The Examiner further alleges that Iimura '081 evidenced that when Y is non-hydrogen, a similar reaction will take place. The Examiner argues that since F is a generally inert substitution, it is expected that the broader scope of the claims when Y is F would operate in similar manner as the unsubstituted indanone thus would be prima facie obvious over the known process in absence of unexpected results.

However, the claims are patentable over the combination of the '337 Dubroeucq, '765 Vidyadhar and '081 Iimura patents for the following reasons. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when

combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). MPEP 2143. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). MPEP 2143.03. It is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. (*KSR v Teleflex*, 12 S.Ct. 1727, 1740 (US 2007)). Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. (*Id.*).

As set forth above, the instantly claimed method does not use acetic acid as a solvent in the hydrogenation reaction, as disclosed in both the ' '337 Dubroeucq patent and '765 Vidyadhar patent. These deficiencies are not cured by the '081 Iimura patent. The '081 Iimura patent discloses a process in which donepezil hydrochloride is prepared by hydrogenating 1-benzyl-4-[(5,6-dimethoxy-1-indanon)-2-yl]methylpyridinium bromide of formula A (see '081 at column 13, example 3):



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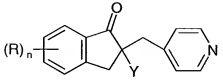
in the presence of platinum oxide catalyst in methanol solvent at room temperature under atmospheric pressure.

However, the instant claims are not drawn to a method of hydrogenating 1-benzyl-4-[(5,6-dimethoxy-1-indanon)-2-yl]methylpyridinium bromide of formula A of the '081 Iimura patent, but instead hydrogenating the compound of formula II:



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which is clearly a different compound from the formula A compound of the '081 Iimura patent, which is a quaternary salt. The instant claims are drawn to a method of hydrogenating the compound of formula II with hydrogen using platinum oxide, palladium-carbon, raney nickel or ruthenium oxide catalyst in the presence of an acid (0.1 to 10 moles of the acid per mole of the compound of formula II, please see page 3, para-0018 of US 2006/0041140) in a suitable solvent (please see page 4, ¶[0033] of US 2006/0041140) under a hydrogen pressure of 1 to 10 bars. Furthermore, the '081 patent does not disclose using acid as a catalyst in the hydrogenation

reaction. Therefore, all the limitations of the claims are not taught or suggested in the combination of the '337 Dubroeucq, '765 Vidyadhar and '081 Iimura patents.

Accordingly, reconsideration and withdrawal of the rejection of pending claims 1-3, 5-10, 14 under to 35 USC § 103(a) is respectfully requested.

* * *

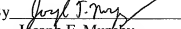
For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

November 2, 2007

By 
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